

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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SHIRE LABORATORIES, INC.,  
Plaintiff,

03 Civ. 1219 (PKC) (DFE)

- against -

OPINION AND ORDER

BARR LABORATORIES, INC.,  
Defendant.

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DOUGLAS F. EATON, United States Magistrate Judge.

Judge Castel received letters from Barr dated January 30, 2006, from Shire dated February 7, and from Barr dated February 17. He also received Barr's Exhibits A through V and Shire's Exhibits 1 through 33. (I will refer to certain of these exhibits as "Ex. \_\_\_\_.") By order dated March 13, he assigned me to hear and determine the issue of whether Shire had violated the protective order. I heard oral argument on March 22, 2006. By letters dated April 10 and 11, Barr submitted Exhibits W, X and Y. Shire then sent me a letter dated April 12. In a Memorandum and Order dated April 25, I directed Shire's attorneys to conduct a search for their pertinent communications with Shire, and to submit them to me *in camera* along with certain sworn statements. In compliance with that order, Shire's attorneys submitted three documents, each dated May 26, 2006. I have reviewed them *in camera*. By letters dated June 6 and 13, Barr requests access to some of the *in camera* material. The *in camera* material is:

1. The 10-page Declaration of Porter F. Fleming Regarding Document Search Methodology and Results. I direct Shire to serve Barr with a copy. I find that Shire's search has been more than adequate.

2. The 22-page Declaration of Porter F. Fleming Regarding Privileged Communications. It annexes the 24 documents found in the search, and explains why it 22 of them are privileged. I agree that they are privileged, but I find it necessary to describe a few portions of them in this Opinion. I deny Barr's request to see this Declaration or documents 1-22. I direct Shire to serve Barr with copies of documents 23 and 24; Barr has already seen them, and Shire does not claim privilege as to them.

3. The 7-page Declaration of Shona McDiarmid. It

annexes copies of the two patents in suit, and copies of Barr's notice letters to Shire dated January 14 and August 15, 2003. I deny Barr's request to see this Declaration, although I find it necessary to quote one portion of it in this Opinion.

Of course, the fact that I have chosen to describe some of the privileged documents does not constitute any waiver or forfeiture of Shire's right to have the remainder protected by the attorney-client privilege and the work-product doctrine.

**Before filing this Opinion, I am faxing it to the attorneys. If either side believes that any portions should be redacted from the publicly filed Opinion, they must fax me their reasons within two business days.**

In this patent infringement case, the Stipulated Protective Order was signed by Judge Marrero on August 1, 2003 (Ex. A). It provided as follows. Each party could designate any document as Confidential Information. Such information was to be "used solely for the purpose of this action." It was to be disclosed only to Qualified Persons, a category that included all outside counsel of record, and two eligible in-house attorneys for Barr, and:

Two in-house attorneys for Shire, namely Tatjana May and Shona McDiarmid, who, after receipt of Barr Confidential Information, and in addition to the other terms of this protective order, (A) shall not be involved in the preparation or prosecution of any patent application that covers Adderall XR ... or Barr's generic version of Adderall XR ... for the duration of the action including appeals, and (B) shall not disclose to the FDA Barr's Confidential Information.

(Ex. A, p. 3, ¶2(g)(I).) It appears to be undisputed that "after receipt" means "after receipt by said in-house attorney."

In September 2003, Barr began producing its Confidential Information to Shire's outside counsel. Shire's outside counsel writes:

As this litigation unfolded, Shire's in-house counsel concluded that there was no need [for in-house counsel] to review Barr confidential information. Thus, neither Dr. McDiarmid nor

Ms. May executed a declaration and agreement to be bound by the protective order [as would have been required by ¶11(b)].

(Edgar Haug's 2/7/06 letter, p. 3.) It appears that the Barr team chose to proceed somewhat differently. One of the two eligible in-house attorneys for Barr was Frederick Killion; he signed such a declaration. Barr's outside counsel have chosen, to date, not to show him any confidential Shire documents, but they may have orally told him some Shire Confidential Information. (3/22/06 Tr. 6-8.)

On July 8, 2004, two of Shire's outside counsel (Peter Bensinger, Jr. of the Bartlit firm in Chicago, and Sandra Kuzmich of the Frommer firm in New York) worked together to prepare two documents: Shire's First Supplemental Responses to Interrogatories Nos. 1 and 13 (Ex. B), and Shire's Second Supplemental Responses to Interrogatories Nos. 2 and 14 (Ex. C). Each of those two Responses had two signature pages, signed by Frommer's Edgar Haug and by in-house attorney Shona McDiarmid. On Ex. B, Mr. Haug's signature was preceded by no preamble; on Ex. C, it was preceded by the phrase "Submitted as to objections stated above." (See 3/22/06 Tr. 12.) On both Ex. B and Ex. C, Ms. McDiarmid's signature was on a separate page, and was preceded by these words:

I hereby verify under penalty of perjury under the laws of the United States of America that the answers in the foregoing ... are true and correct to the best of my knowledge and belief.

Ex. B consisted primarily of a claim chart (small portions of which referred to Barr Confidential Information) and two exhibits. Ex. C consisted primarily of a claim chart (large portions of which referred to Barr Confidential Information) and three exhibits (one of which was Barr Confidential Information).

Five months later, Barr's counsel stated (in Ex. F, by strong implication) his understanding that Ms. McDiarmid had received Barr Confidential Information. Shire's counsel promptly denied this (Ex. S) and in January 2005 provided declarations from Ms. McDiarmid, Ms. Kuzmich and Mr. Bensinger (Exs. K, L, M). Ms. McDiarmid's declaration (Ex. L) said, in part:

8. Prior to signing the [7/8/04] Verification [to Ex. C] I did not review the written text of the interrogatory responses, which were prepared by Shire's outside counsel.

9. Prior to signing the Verification I had discussions with Shire's outside counsel regarding the response. During these discussions no Barr confidential information was disclosed to me by Shire's counsel.

10. Based on the advice of counsel, I was able to verify that the responses prepared by Shire's counsel were "true and correct to the best of my knowledge and belief."

11. At no time have I received directly or indirectly any Barr confidential information.

Mr. Bensinger's declaration (Ex. M) said, in part:

2. From February 24, 2003 until October 26, 2004, Bartlit Beck was co-counsel for plaintiff Shire ... along with Frommer Lawrence & Haug ... .

\* \* \*

7. Before Ms. McDiarmid signed the [7/8/04] Verification [to Ex. C], I explained to her the general subject matter of the interrogatories and Shire's responses thereto [which I prepared together with Dr. Sandy Kuzmich, Esq. of the Frommer firm]. I explained that the responses were based in part on confidential Barr information and that the responses accurately reflected the views of Shire's outside counsel, who were permitted to see Barr confidential information. At no time did I reveal to Ms. McDiarmid the substance or particulars of any Barr confidential information.

Ms. Kuzmich's declaration (Ex. L) was very similar.

In such a situation, Rule 33(a) provides that a corporation may answer interrogatories "by any officer or agent." "Agent" includes an **outside** attorney for the corporation. *Wilson v. Volkswagen of America, Inc.*, 561 F.2d 494, 508 (4th Cir. 1977). When I heard oral argument, I mentioned this and asked "why is it that Shire used Ms. McDiarmid's certification"? (3/22/06 Tr. 3.) Mr. Fleming answered:

... [O]ur co-counsel, the Bartlit Beck firm, believed that verifications from **inhouse** counsel

were necessary. And as part of that co-counsel relationship with the Chicago firm, we [the Frommer firm] did submit [those] verifications.

(3/22/06 Tr. 4, with my emphasis.)

On February 24, 2005, Barr deposed Ms. McDiarmid and she testified as follows. She verified Shire answers to other interrogatories in September 2003, February 2004, May 2004, August 2004, and September 2004, and believed that she read each answer before verifying. (Ex. J at Tr. 148-50, 153-57.) However, she verified the July 2004 answers without reading them, because it was her understanding that they contained Barr Confidential Information. (*Id.* at Tr. 159, 169.) Barr asserts: "Reading the interrogatory answers is a prerequisite to verifying them." (1/30/06 letter to J. Castel, p. 8.) I disagree, at least where the answering party is a corporation. The main point of the signature is to bind the party. Barr quotes from *Gargiulo v. MGI Communications*, 1992 WL 22242, at \*2 (E.D. Pa. Feb. 5, 1992) ("it is his client who must read and sign them"). I do not view the verb "read" as a holding; moreover, the answering parties were 12 individuals and only one corporation. Judge VanArtsdalen cited only one authority, the 1970 edition of Wright & Miller. I do not have that edition, but the current edition does not say that the client "must read" the answers; it merely says "the common practice is for the attorney to prepare the answers and have the party swear to them." 8A Wright, Miller & Marcus, *Federal Practice and Procedure*, §2172, pp. 282-83 (1994 ed.). The D.C. Circuit has written:

... Of course, the [corporate] representative must have a basis for signing the responses and for thereby stating on behalf of the corporation that the responses are accurate. The representative may accomplish this through whatever internal process the corporation has chosen, including discussions with counsel.

*Shepherd v. American Broadcasting Cos., Inc.*, 62 F.3d 1469, 1482 (D.C. Cir. 1995). In *Gucci America, Inc. v. Exclusive Imports Int'l*, 2002 WL 1870293, at \*7 (S.D.N.Y. Aug. 13, 2002), Judge Casey ruled that Gucci's answers were proper and binding even though the verifying officer "had no knowledge of the substantive truth of the interrogatory responses and had taken no independent verification of the facts asserted, but had instead relied upon information furnished by counsel."

In the case at bar, as noted in Mr. Bensinger's declaration,

the Bartlit firm ceased being a co-counsel on October 26, 2004. From then on, the Frommer firm has been the sole outside counsel of record for Shire in this lawsuit. On December 10, 2004, the Frommer firm prepared some more answers, this time to Barr's Fourth Set of Interrogatories. These answers, like the July 2004 answers, contained some Barr Confidential Information. This time, however, the Frommer firm did not follow the Bartlit firm's practice of asking an employee of Shire to sign. Instead, Ms. Kuzmich signed the answers as an outside attorney for Shire. (Ex. W.) As I mentioned earlier, this option was entirely proper under Rule 33(a). However, perhaps because these were contention interrogatories, Ms. Kuzmich failed to add specific words stating that she was verifying that the answers were true. By letter dated December 15, 2004, Barr's counsel asked for "a signed verification." (Ex. X, at the end.)

Frommer associate Nathan D. Weber replied in a short letter dated December 17, 2004 (Ex. T). He seemed to overlook the possibility that Ms. Kuzmich could simply re-sign after adding words of verification. Instead, he wrote:

... [U]nder the Protective Order, Barr confidential information cannot be shown to any individual at Shire. Accordingly no verification is currently possible without violating the Protective Order.

That language was overbroad. Ms. McDiarmid had recently left the employ of Shire, but the other designated in-house attorney, General Counsel Tatjana May, was available. She could have signed a verification if she had elected to follow either of two options:

1. She could have elected to sign the declaration and agreement to be bound (the document required by ¶11(b) of the Protective Order). In that event, she could review Barr Confidential Information but, after receiving it, she could "not be involved in the preparation or prosecution of any patent application that covers Adderal XR." Such a patent application was being prosecuted by Shire in late 2004. (See Ex. D.)

2. Alternatively, the Frommer firm could have followed the Bartlit firm's practice: merely tell Ms. May that Shire's outside counsel believed the answers to be accurate and ask Ms. May to sign a separate verification page without reading the

answers, since they contained some Barr Confidential Information.

However, neither option was obligatory. The signature of Shire's outside counsel Ms. Kuzmich would be sufficient, provided that she adds words of verification and re-signs her 12/10/04 answers. (If she has not done so already, I direct her to do so within 10 business days.) But Barr's main point is that Barr asks me to view Mr. Weber's 12/17/04 letter as evidence that Ms. McDiarmid's July 2004 verification means that she received some Barr Confidential Information. I view it as no such evidence.

Next, Barr points to the fact that Ms. McDiarmid, near the end of her employment at Shire, accompanied a Shire employee and Anthony Zelano (a Washington attorney retained by Shire) to a meeting at the U.S. Patent Office with Supervisory Patent Examiner Thurman K. Page. This meeting, held on November 4, 2004, concerned a Shire application for an additional patent that relates to Adderall XR. It is undisputed that the Protective Order barred her from doing so, if she had received any Barr Confidential Information in or after December 2003. (Ex. A, p. 3, ¶2(g).) Moreover, I will assume, for the purposes of Barr's motion, that Ms. McDiarmid was involved in all stages of Shire's preparation and prosecution of the application for this additional patent. (The application was allowed by the Patent Office on December 17, 2004 and has resulted in the '768 patent.) The context was as follows.

September 24, 2002. Shire filed a provisional application (Ex. 17.) It stated that the invention encompassed sustained-release matrices of various types, including matrices formed from a specific material that was named, more than a year later, in the Barr Confidential Information. (Ex. 17 at pp. 5-6; Ex. 29.)

January 14, 2003. Barr sent Shire a letter notifying Shire (a) that Barr had filed an Abbreviated New Drug Application ("ANDA") for generic Adderall XR capsules and (b) that Barr had submitted a paragraph IV certification against an earlier Shire patent, the '819 patent. (Ex. 30.) Barr's notice told Shire the active ingredients in Barr's proposed product, including amphetamine aspartate. (Ex. 30, p. 2.)

January 29, 2003. Shire filed a utility application (Ex. 18) to initiate the Patent Office's examination of the application for the additional patent.

October 6, 2004. The Patent Office acted on the application, cited certain prior art, and rejected certain of

Shire's claims. (Ex. 20.)

November 4, 2004. Ms. McDiarmid accompanied a Shire employee and Shire's Washington attorney Mr. Zelano to the meeting at the U.S. Patent Office. In the interview summary (Ex. D, a public document) the Patent Examiner listed the participants, identified three items of prior art, and then wrote:

Discussed distinctions between prior art rates of release and compared applicants' continuous single release formulations. Suggested claims be amended to recite specific formulations that result in the plasma profiles in Fig. 1. Specific formulations not recited in the prior art along with those not suggested are allowable.

November 23, 2004. In response to the Patent Examiner's suggestion, Shire amended its claims to recite more specific formulation language. The replacement language came directly from the specification filed by Shire in 2002. (See Shire's 2/7/06 letter to Judge Castel, at pp. 8-12.) Those amendments do not show that Mr. Zelano or Ms. McDiarmid (or anyone else outside the Frommer and Bartlit firms) possessed any of the Barr Confidential Information.

As mentioned above at pages 3-4, Shire served declarations from Ms. McDiarmid, Mr. Bensinger and Ms. Kuzmich in January 2005, and the next month Barr took the deposition of Ms. McDiarmid. The transcript is Ex. J, and I shall now discuss her testimony in more detail.

At Depo. Tr. 157-67 she testified about her involvement in the preparation of answers to Interrogatories Nos. 1 and 13, which concerned claim construction. She testified that she believed she reviewed some draft answers and "they would have been redacted drafts," redacted to exclude "confidential information of Barr." (Depo. Tr. 159-60.)

At Depo. Tr. 167-71 she testified about her involvement in the preparation of answers to Interrogatories Nos. 2 and 14, which concerned infringement contentions. She testified that she had conversations with "Peter Bensinger, and possibly Sandra Kuzmich," and that she was not given any drafts or redacted responses for Nos. 2 and 14. (Tr. 169-70.)

A year later, Barr asked me to require Shire to produce "the



draft interrogatory answers that Ms. McDiarmid said that she did read." (3/22/06 Tr. 42.) On April 25, 2006, I ordered Shire to produce these and certain other documents to me for my *in camera* review. On May 26, Shire complied with my order. In my view, Privileged Communications 16, 17 and 18 provide clear and convincing evidence that corroborates Ms. McDiarmid's testimony.

Privileged Communication 16, dated July 6, 2004, is an e-mail from Mr. Bensinger to his clients Ms. McDiarmid and Ms. May. It starts with a two-page discussion of legal strategy that does not mention any Barr Confidential Information. It annexes a 17-page draft of the responses to Interrogatories Nos. 1 and 13, and this version contains no Barr Confidential Information.

Privileged Communication 17, dated July 7, 2004, is another e-mail from Mr. Bensinger to Ms. McDiarmid and Ms. May. It starts with a one-page discussion of legal strategy that does not mention any Barr Confidential Information and says (with my emphasis):

I attach a **revised** version of Shire's draft interrogatory response on claims construction. We have **redacted** confidential Barr information from the deposition of Barr's formulator.

It annexes a 19-page draft of the responses to Interrogatories Nos. 1 and 13. Mr. Bensinger sent this draft in PDF format so that it would be impossible for Ms. McDiarmid or Ms. May to view his blacked-out redactions. These redactions occurred in two passages, both of which are at the point in the claim chart that construes the fourth portion of Claim 1. First, this draft supplemented the previous day's draft by adding a passage of nine lines plus two words, but Ms. McDiarmid and Ms. May were able to see only the following parts of this new passage:

... Barr's formulator Mr. Hossain, who worked on the development of Barr's generic version of Adderall XR (see Hossain Dep. Rough Draft p. 20, 1.17 - p. 22, 1.23) understood that [REDACTED] (see Hossain Dep. Tr. Rough Draft p. 136, 1.24 - p. 137, 1.4). Mr. Hossain [REDACTED]  
[REDACTED]  
[REDACTED] See Hossain Dep. Tr. Rough Draft p. 140, 1.21 - p. 141, 1.13.

Second, this draft supplemented the previous day's draft by adding a passage of five lines plus one word, but Shire's inhouse attorneys were able to see only the following parts of this new passage:

... See also Hossain Dep Tr.  
Rough Draft, p. 24, l.23 - p. 26, l.9 (stating that  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]) .

In short, Mr. Bensinger meticulously ensured that Ms. McDiarmid and Ms. May did not see the Barr Confidential Information. His Privileged Communication 17 also enclosed a separate verification page for Ms. McDiarmid to sign as to Interrogatories Nos. 1 and 13.

A few hours later, also on July 7, 2004, Mr. Bensinger sent an e-mail dealing with Interrogatories Nos. 2 and 14. This is Privileged Communication 18. It went only to Ms. McDiarmid (with a copy to Ms. Kuzmich of the Frommer firm). It contained nothing but a verification page for Ms. McDiarmid to sign as to Interrogatories Nos. 2 and 14. This is congruent with her testimony that she received no draft answers as to Nos. 2 and 14. In her 5/26/06 *in camera* Declaration, at ¶18, Ms. McDiarmid confirms that she never reviewed even a redacted version of the responses to Nos. 2 and 14, and she explains:

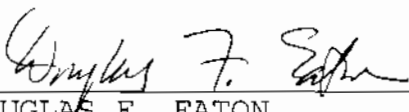
18. Mr. Bensinger, Dr. Kuzmich and I discussed whether I should review a redacted version of Shire's responses to interrogatories 2 and 14 in which all Barr confidential material was removed; they informed me such a review would be futile given the extent of the redactions [that would be needed in the responses to 2 and 14].  
...

I am confident that Mr. Bensinger told her this. If Ms. Kuzmich was on the telephone during that portion of the discussion, I think it is likely that she was not paying close attention. I say this because of Privileged Communications 21 and 22. Privileged Communication 21 is an e-mail to Ms. Kuzmich dated July 12, 2004 from Ms. May, who simply wrote: "Please send me a copy of the documents we gave the judge last Friday." In less than a minute, Ms. Kuzmich responded: "I will have the Barr confidential material redacted and then have the redacted documents forwarded to you. Please let me know if you need

anything else." Of course, this shows that the attorneys were being mindful of the need to redact. I find that, in all likelihood, Ms. Kuzmich then contacted Mr. Bensinger, who (directly or indirectly) advised Ms. May, in substance, as follows: As to Interrogatories Nos. 1 and 13, the responses were given to Barr's counsel (not to the judge) and their wording was the same as the draft sent to you on July 7 except Barr's counsel saw the portions that I redacted in the copy sent to you. As to Interrogatories Nos. 2 and 14, it would be futile to prepare a redacted version of the responses because those redactions would have to be very extensive.

#### CONCLUSION

I conclude that Shire has not violated the Protective Order. In my view, Barr has tried to make a mountain out of a molehill. It has slowed up Shire's lawsuit, and caused Shire's inhouse and outside attorneys to spend a great deal of time to demonstrate that they have been telling the truth. Judge Castel referred this matter to me to hear and determine under Rule 72(a), Fed.R.Civ.P. If Barr chooses to appeal my ruling to Judge Castel, I would recommend that Judge Castel consider awarding Shire reimbursement for its costs, including attorneys' fees, in defending against any such appeal if the appeal is unsuccessful.

  
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Dated: New York, New York  
June 23, 2006

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